I. Status of the claims

Applicants elected claims 30-48 on May 20, 2002 in response to a Restriction Requirement (Paper No. 9). Applicants were further required to elect a species for examination and indicate which claims were generic to the elected species. The species of nucleotides (claim 31) was elected by the Applicants and claims 30 and 34-48 were indicated as being generic to the elected species.

In the Office Action of August 9, 2002, the Examiner withdrew Claims 31-33 from consideration, stating that they were "...drawn to nonelected inventions and species, there being no allowable generic or linking claim." However, Applicants note that Claim 31 recites that the target and capture molecules are nucleotide sequences. Accordingly, Applicants note that Claim 31 is within the elected group and Applicants respectfully request that this claim be examined in the present application as amended above.

II. The present invention is enabled

The Examiner has rejected claims 30 and 34-48 under 35 U.S.C. § 112, first paragraph on the assertion that the specification is non-enabling for:

a. the detection of any number of samples of DNA or RNA on a CD support;

b. the use of radiation, magnetic fields, "chemo, bio, fluoro, radioactivity, electroluminescence light, radiation";

c. the corrosion of one or more layers of the disc;

d. the use of one or more microbeads or magnetic particles;

e. where the disc comprises "micro-channels connected and in fluid contact"; or

f. where binary registration data is on the disc or the use of said data in the "treatment and interpretation of the signal."

The Examiner further asserts that under the *In re Wands* factors the specification is non-enabling due to undue experimentation due to the limited number of working examples, the invention being in the unpredictable chemical field, the high level of skill in the art, and the breadth/scope of the claims.

As recited in claim 30, the present invention is a "method for the detection of a target molecule present in a sample, comprising the steps of: allowing binding between said target molecule and a capture molecule fixed upon a side of the surface of a solid support, said solid support comprising a disc, wherein said binding results in a detectable signal, and wherein said

disc comprises registered data located on areas separated from the areas where the signal is generated; detecting said signal, wherein said signal is not obtained through cleavage of the capture molecule, and reading the registered information and reading the signal resulting from the binding between said target molecule and said capture molecule, said readings being done by two different reading devices."

Applicants submit that the presently claimed invention is fully enabled for the recited methods. The specification teaches several types of target and capture molecules (pages 14 (line 23) through page 17). Methods of fixing the capture molecules of the invention to the surface of the support are found on pages 18 to 20 and Examples 1 and 2 of the specification as filed.

Methods for detecting binding between the capture and target molecules are disclosed on pages 16-26 of the specification. In addition, with respect to the species currently under examination in which the target and capture molecules are nucleotide sequences, methods of fixing the capture molecules to the disc and detecting binding between the capture molecules and the target molecules are specifically exemplified in Examples 1, 2 and 5. The detection methods specifically exemplified are variations of the well known biotin/streptavidin labeling system with secondary labels of 1) peroxidase with TMB for light absorption detection, and 2) colloidal gold and Silver enhancement for laser detection of a silver precipitate. Figures 2 and 3 of the specification as filed depict the laser detection of the silver precipitate. In addition, the specification has prophetic Example 5 which is related to a magnetic detection of nucleic acids (DNA) or proteins on a CD and is illustrated in Figure 7 of the filed specification. Thus, contrary to the Examiner's assertion, Applicants have enabled a variety of detection technologies, including light absorption, laser detection and magnetic detection systems.

With respect to embodiments employing microparticles, the Examiner asserts that the microparticles on the disc could easily be discharged from the surface of the disc when undergoing spinning at a high rate of speed or that such spinning could result in movement of the microparticles to another region of the disc, resulting in corruption of the data obtained in a method of the invention. Applicants submit that this is not the case. Example 2 and Figures 2 and 3 describe the detection of nucleotide sequences using colloidal gold particles. The Examples indicate that microparticles present upon the surface of the disc will not affect the detection of the nucleic acid molecules due to the specific hybridization (binding) of the nucleic acid target molecule to its capture molecule by the specified detection methods.

Regarding points b), c) and e) in the above rejection, Applicant notes that although Applicant maintains that all aspects of the previous pending claims are patentable and enabled by the present application, for the purposes of expediting prosecution of the present application, the pending claims have been amended such that they are not directed towards the use of radiation, bio, chemo or radioactivity as stated in point b) above; nor are they directed towards the corrosion of one or more layers of the disc as stated in point c) above; and they are not directed towards a method where the disc comprises "micro-channels connected and in fluid contact" as stated in point e) above. Therefore, Applicants submit that in light of the cancellation of claims 42 and 48 and amendments to the pending claims, these rejections are not applicable.

In light of the above remarks, Applicants respectfully request withdrawal of the rejection to claims 30 and 34-48 under 35 U.S.C. § 112, first paragraph.

III. The presently-claimed invention is novel and non-obvious

The Examiner has rejected claims 30 and 34-48 under 35 U.S.C. § 102(e) or in the alternative under 35 U.S.C. § 103(a) over Virtanen (USP# 6,030,581), on the assertion that Virtanen teaches the use of a disc in the performance of various nucleic acid assays that can be read by a CD or DVD player, that microspheres are disclosed, as is the recording of information onto a disc which may relate to the spatial address or information related to the assay, various detection means including fluorescent dyes, and that Virtanen discloses using spectrophotometric assays.

Novelty over Virtanen

M.P.E.P. 2131 states that to anticipate a claim, the reference must teach every element of the claim. (Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987))

The present invention is a "method for the detection of a target molecule present in a sample, comprising...allowing binding between said target molecule and a capture molecule fixed upon a side of the surface of a solid support...detecting said signal, wherein said signal is not obtained through cleavage of capture molecule..." as recited in Claim 30.

In the methods disclosed in Virtanen, the signal is detected after cleaving a spacer. (*see* col. 9, lines 1-12; col. 9, line 65-col. 10, line 18: and throughout the Examples, for example, at col. 13, lines 1-6, 29-37, and 46-57). In the presently-claimed method, the signal is not obtained

through cleavage as recited in claim 1. Accordingly, Virtanen does not teach every element of the claim as required by M.P.E.P. 2131.

Therefore, Applicants request withdrawal of the rejection under 35 U.S.C. § 102(e) to claim 30 and 34-48.

Non-obvious over Virtanen

M.P.E.P. 2143 requires that to make a claim obvious there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, there must be a reasonable expectation of success and the prior art reference must teach or suggest all the claim limitations.

As discussed above, Virtanen does not anticipate the presently-claimed invention since Virtanen teaches detection after cleaving a spacer. There is no suggestion to use a method where the detection does not include cleavage of the capture molecule (spacer). The methods disclosed in Virtanen include enzymatic cleavage of the spacer (*see*, for example, col. 13, lines 4-5; 52-56). Therefore, the reference provides no motivation to modify its teachings to arrive at the presently-claimed invention since Virtanen requires cleavage of a spacer for detection. Thus, Virtanen fails to make obvious the presently-claimed invention since it does not teach a method which involves detection of a signal without cleavage of a capture molecule.

Since the requirements for obviousness are not met by the cited Virtanen reference, Applicants respectfully request withdrawal of the rejection to claims 30 and 34-48 under 35 U.S.C. § 103(a).

IV. Conclusion

Claims 42 and 48 have been canceled, all without prejudice and claims 30 and 36-39 have been amended. The amendments to the claims are supported throughout the specification as filed. Thus, no new matter has been added herewith. In addition, Applicants have requested reconsideration of claim 31 and have presented an amendment to the claim to be entered upon Examiner's acceptance of the reconsideration. This amendment is supported throughout the specification as filed. The changes made to the claims by the current amendment, including insertions and **[deletions]**, are shown on an attached sheet entitled **VERSION WITH**

MARKINGS TO SHOW CHANGES MADE, which follows the signature page of this amendment. No new matter has been added herewith.

In view of the foregoing, Applicants respectfully submit the present application is fully in condition for allowance. If any issues remain that may be addressed by a phone conversation, the Examiner is invited to contact the undersigned at the phone number listed below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

The heading at line 8, page 28 has been amended to:

Example 2: Detection of DNA on CD with laser detection

In the claims:

30. **(Amended)** A method for the detection of a target molecule present in a sample, comprising the steps of:

allowing binding between said target molecule and a capture molecule fixed upon a side of the surface of a solid support, said solid support comprising a disc, wherein said binding results in a detectable signal, and wherein said disc comprises registered data located on areas separated from the areas where the signal is generated;

detecting said signal, wherein said signal is not obtained through cleavage of the capture molecule, and

reading the registered information and reading the signal resulting from the binding between said target molecule and said capture molecule, said readings being done by two different reading devices.

36. **(Amended)** The method according to Claim 35, wherein the emission is generated by a bound molecule which is selected from the group consisting of molecules having **[chemo, bio,]** fluoro**[, radioactivity,]** and electroluminescence light**[, and radiation]**.

37. **(Amended)** The method of Claim 30, wherein said detecting step comprises detecting a direct emission of a light beam**[, a radiation]** or a magnetic field, resulting from the binding between the target molecule and the capture molecule.

38. **(Amended)** The method according to Claim 37, wherein the emission is generated by a bound molecule which is selected from the group consisting of molecules having **[chemo, bio,]** fluoro**[, radioactivity,]** and electroluminescence light**[, and radiation]**.

39. **(Amended)** The method of Claim 30, wherein the signal comprises a precipitate upon the surface of the disc**[and/or the corrosion of one or more layer(s) of the surface of the disc]**.

Claims 42 and 48 have been canceled.